K120718

510(k) Summary of Safety

APR 19 2012

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

February 19, 2012

Submitter's Information: 21 CFR 807.92(a)(1)

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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	InstaPACS™/InstaRISPACS™
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050 System, Image Processing
Product Code:	LLZ

Predicate Device: 21 CFR 807. 92(a)(3)

InstaPACS™/InstaRISPACS™ is substantially equivalent to:

Device Classification Name	system, image processing, radiological
510(k) Number	K080334
Device Name	InstaRAD
Applicant	MEDSPHERE TECHNOLOGIES PVT LTD.
Regulation Number	892.2050
Classification Product Code	LLZ
Decision Date	02/21/2008
Decision	substantially equivalent (SE)
Classification Advisory Committee	Radiology

Device Description: 21 CFR 807 92(a)(4)

InstaPACS™/InstaRISPACS™ is a software application used for viewing and manipulating medical images. Digital images and data from various sources (including CT, MR, US, RF units, computed and direct radiographic devices, secondary capture devices, scanners, imaging gateways, or imaging sources) can be displayed, processed, stored and communicated across computer networks using this software. When viewing images, users can perform adjustments of window width and level, annotation, and various image

manipulations. In addition, the device can be integrated with an institution's existing Hospital Information System or Radiology Information System (based on the study), providing seamless access to reports for fully-integrated electronic patient records.

InstaPACS™/InstaRISPACS™ allows multiple centers or hospitals to send their images to a central server where Radiologists can view images over Web. It consists of following components:

- Central Server - runs the Web Server and Image Server and provide study and image data to doctors. The server includes a DICOM Gateway Application which is deployed at remote centers or hospitals. It receives images from modalities over LAN and uploads them to central server
- WorkStation - User at the client side can access the study list in the browser. They can select the patient and download the images.

Indications for Use: 21 CFR 807 92(a)(5)

InstaPACS™/InstaRISPACS ™ is a software device (DICOM Gateway Application, Enterprise Server, and Workstation) used for viewing and manipulating digital medical images. Digital images (including mammography and data from various sources (including CT, MR, US, RF units, computed and direct radiographic devices, secondary capture devices, scanners, imaging gateways, or imaging sources) can be displayed, processed, stored and communicated across computer networks using this software. InstaPACS™/InstaRISPACS™ can be integrated with an institution's existing Hospital Information System (HIS) or Radiology Information System (RIS) based on the study of the System, providing seamless access to reports for fully-integrated electronic patient records. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 MPixel resolution and meets other technical specifications reviewed and accepted by FDA.

Technological Characteristics: 21 CFR 807 92(a)(6)

InstaPACS™/InstaRISPACS ™ device is a software product that handles digital medical images. The device does not contact the patient, nor does it control any life sustaining devices. Diagnosis is not performed by the software but by Radiologists, Clinicians and referring Physicians. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

The new device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The new device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices.

Nonclinical Testing:

The complete system configuration has been assessed and tested at the factory and has passed all predetermined in-house testing criteria. The Validation Test Plan was designed to evaluate all input functions, output functions, and actions performed by the InstaPACS™/InstaRISPACS ™ software in each operational mode and followed the process documented in the System Validation Test Plan.

510(k) Summary of Safety

Nonclinical testing results are provided in the 510(k). Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for InstaPACS™/InstaRISPACS ™ contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device.

The subject device will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The new device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

Therefore, InstaPACS™/InstaRISPACS ™ is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MEDDIFF Technologies Pvt. Ltd.
% Mr. Carl Alletto
Official Correspondent
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APR 19 2012

Re: K120718
Trade/Device Name: InstaPACS™/InstaRISPACS™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 7, 2012
Received: April 12, 2012

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K120718

Indications for Use

510(k) Number (if known):

Device Name:
InstaPACS™/InstaRISPACS™

Indications for Use:

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Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K120718